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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,283	11/13/2001	Carl-Axel Bauer	06275-150003	5064

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,283	Carl-Axel Bauer et al.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 11-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 11-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/18/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

The response filed December 20, 2004 have been received and entered into the application.

Action Summary

The rejection of claims 9 and 11-25 under 35 U.S.C. 103(a) as being unpatentable over Carling et al. of record in view of (Cazzola et al. (U) of record and Andersson et al. (U.S.Patent No. 6598603B1) and further in view of Giardina et al. (U.S.Patent No. 6,277,862B1) is hereby expressly withdrawn because Applicant's arguments, with respect to the Andersson et al. (U.S.Patent No. 6,598,603 B1), have been fully considered and are persuasive. Therefore the Andersson et al. is withdrawn as a reference and the rejection is modified herein.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 9 and 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling et al. of record in view of (Cazzola et al (U) of record and Renkema et al. (Chest, 1996) and further in view of Giardina et al. (U.S.Patent No. 6,277,862B1) of record.

Carling et al. on the abstract, page 4, lines 23-29, page 7-9(examples), and page 10 (claims), teach a medicament containing effective amounts of formoterol and budesonide in combination for simultaneous, sequential or separate administration by inhalation in treatment of respiratory disorder with effective amounts within Applicants' range set forth in claim 9. Carling et al. teach that the combination comprising formoterol and budesonide has not only a greater efficiency and duration of bronchodilator action but the combination also has a rapid onset of action and this new feature is of utmost importance in order to establish a higher compliance for patients and it provides a rescue medicine thereby avoiding the necessity for the patient of carrying two different inhalers. (page 4, lines 4-10). Carling et al. teach that the combination of formoterol and budesonide in a single formulation simplifies life for patients considerably and makes life more comfortable and secure in treating respiratory disorder. (page 4, lines 10-12, lines 23-29).

Carling et al. do not expressly teach the treatment of COPD.

Cazzola et al. on the abstract teaches that formoterol is effective in patients with COPD.

Renkema et al. teaches the effects of long-term treatment with corticosteroids (i.e. budesonide) in COPD. (abstract). Renkema et al. teach that the treatment with

corticosteroid (i.e. budesonide) significantly reduced pulmonary symptoms in patients with COPD. (abstract).

Giardina et al. report that COPD and asthma are respiratory diseases. (column 1, lines 37-40, column 5, lines 55-57, claim 47).

It would have been obvious to skilled artisan to employ the Carling's medicament in treatment of COPD since COPD is well known respiratory disease as disclosed by Giardina et al. Further, each of active agents (budesonide and formoterol) utilized in Carling's medicament are individually known to treat COPD conditions as well as taught by Cazzola et al. Renkema et al.. One of ordinary skilled in the art would have been motivated to employ Carling's medicament in treatment of COPD with reasonable expectation of success since each of the active agents utilized in Carling's medicament are well known individually for treating respiratory disease, COPD. Absent any evidence to contrary, there would have been a reasonable expectation of successfully treating COPD by employing Carling's formulation to achieve greater efficiency and duration of action with a rapid onset of action and to simplify life for COPD patients by making life more comfortable and secure in treating respiratory disease (e.g. COPD).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Arguments

Applican"s arguments filed December 20, 2004 have been fully considered but they are not persuasive. Applicants argue that the context of the Carling et al. reference teaching of "asthma and other respiratory disorder" does not mean "asthma and **all other** respiratory disorders" as there is no reason to expect the drug combination taught by Carling et al. have any value for treating such widely disparate reparatory disorder as say lung cancer, adult respiratory distress syndrome or cough. This is not persuasive because Carling et al. clearly teaches the combination is useful for the treatment of asthma and other respiratory disorders and Giardina et al. disclose that chronic obstructive pulmonary disease (COPD) and asthma are referred to as reparatory diseases. Therefore, there is a reasonable expectation of successfully treating other respiratory disease such as COPD in addition to asthma by administration of the combination comprising budesonide and formoterol well taught by Carling et al. for the treatment of asthma and other respiratory diseases. Applicants argue that Giardina et al. was not focused at all on asthma or any other particular condition (respiratory or otherwise) because Giardina et al. proposed using tachykinin receptor antagonists to treat an extraordinarily side variety of conditions, most of which having nothing to do with the respiratory system (see column 1, line 37 through column 2, line 17). This is not persuasive because Giardina et al. lists specific respiratory disease particularly COPD, asthma and airway hyperactivity and cough. Therefore, Giardina et al. clearly discloses COPD as specific respiratory diseases along with asthma as related respiratory conditions. Applicants argue that as explained in the Trofast declaration,

taking into account the context of the Carling et al. reference, the phrase "other respiratory disorders" in Carling et al. "would have been understood to refer to reparatory disorders similar to asthma, i.e. mainly of bronchospastic nature" (page 2, section 5 of the Declaration). The Declaration including page 2, section 5 has been carefully considered. However, this is not persuasive because Giardina et al. particularly mentions four conditions above including COPD and asthma. Therefore, it would be obvious to one of ordinary skill in the art to interpret other respiratory disorder to encompass particularly COPD and asthma as disclosed by Giardina et al. Applicants argue Engel et al. reports that budesonide did not improve symptom scores, ventilatory capacity, or airway responsiveness in subjects with chronic bronchitis (see the abstract), while Watson et al. reports that inhaled budesonide failed to improve symptoms in middle-aged make smokers with mid airway obstruction (see the abstract). This is not persuasive because Renkema et al. teaches the effect of budesonide in long-term treatment in COPD patients having significantly reduced pulmonary symptoms. Therefore, there is a reasonable expectation of successfully treating COPD with combination of budesonide and formoterol both known to have same utility of treating COPD. Applicants' argue that at the time the invention was made, budesonide was not believed to be suitable for treatment of COPD conditions and Keating et al. reports that in COPD patients, inhaled budesonide resulted in no clinical benefit in either lung function or symptoms scores, and no significant changes in the inflammatory indices assayed. This is not persuasive because Renkema et al. teach that inhaled budesonide significantly reduced pulmonary symptoms in COPD patients. Therefore, this teaching

clearly establishes the beneficial effect of budesonide in patients with COPD conditions. Applicants next argue that while Cazzola does teach the use of formoterol to treat COPD, this teaching would not have suggested the use of the budesonide/formoterol combination to treat COPD, in view of the overwhelming evidence that budesonide would not be successful in treating COPD. This is not persuasive because each of the active agent to be utilized are individually known to treat COPD and the active agents are known to be combined in a single formulation for the treatment of respiratory disorders. One of ordinary skill in the art would obviously employ the combination effective for the treatment of respiratory disorders known by Carling et al. for the treatment of COPD in order to achieve an additional beneficial effect in lung symptoms by incorporating budesonide to formoterol regimen in COPD patients. Applicants argue that the unexpected synergistic effects of budesonide and formoterol on the treatment of COPD described in the declaration by Christer Hultquist, M.D., submitted December 13, 2002 and Calverely et al.'s report, Applicants request that the Examiner reconsider the declaration and Calverely et al's report with respect to the obviousness rejection. This is not persuasive because the declaration and Calverely et al's report have been carefully reviewed with respect to the obviousness rejection and it is not persuasive for the reasons set forth in final Office Action that Applicants' claims are not drawn to alleged synergism. To this response, the evidence of synergism provided in the declaration is not commensurate in scope with the breadth of the claims sought to be patented. Claims must be commensurate in scope (synergism) and this is deemed proper since both the combination and its utility is well-known to treat respiratory

disorder as taught by Carling et al. and formoterol and budesonide is effective and beneficial alone for the treatment of COPD (respiratory disorder). Therefore the treatment of COPD utilizing Carling et al's combination is obvious. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
May 1, 2005